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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,627	02/27/2006	An Haoyun	6319-4015	7011
29858	7590 07/12/2006		EXAMINER	
BROWN, RAYSMAN, MILLSTEIN, FELDER & STEINER LLP 900 THIRD AVENUE			MCINTOSH III, TRAVISS C	
NEW YORK,		ART UNIT		PAPER NUMBER
			1623	
			DATE MAILED: 07/12/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
Office Action Summary		10/530,627	HAOYUN ET AL.				
		Examiner	Art Unit				
		Traviss C. McIntosh	1623				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPLICATION OF THE MAILING ENGINEERS IS LONGER, FROM THE MAILING ENGINEERS IN 1997. THE 1997. THE MAILING ENGINEERS IN 1997. T	DATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tinded will apply and will expire SIX (6) MONTHS from the cause the application to become ABANDONE	N. mely filed the mailing date of this communication. ED (35 U.S.C. § 133).				
Status							
1) 🛛	Responsive to communication(s) filed on 18 M	Mav 2006.					
2a)□		s action is non-final.					
3)	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.						
Dispositi	on of Claims						
4)⊠	4)⊠ Claim(s) <u>1-11</u> is/are pending in the application.						
	4a) Of the above claim(s) is/are withdrawn from consideration.						
	☐ Claim(s) is/are allowed.						
· · · · · · · · · · · · · · · · · · ·	Claim(s) <u>1-11</u> is/are rejected.						
7)	Claim(s) is/are objected to.						
8)□	8) Claim(s) are subject to restriction and/or election requirement.						
Applicati	on Papers						
9)	The specification is objected to by the Examina	er.					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority u	ınder 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
۵,۲	1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No						
	3. Copies of the certified copies of the priority documents have been received in this National Stage						
	application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment	i(s)						
	e of References Cited (PTO-892)	4) Interview Summary					
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date Notice of Informal Patent Application (PTO-15)							
Paper No(s)/Mail Date 6) Other:							

DETAILED ACTION

Claim Objections

Claim 8 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that claim 1 requires that the C2', C3', and C5'-atoms comprise an –OH group and claim 8 attempts to expand, and not limit claim 1, by indicating that the –OH groups are no longer present and are replaced by various other functional groups.

Dependent claims should limit the claims from which they depend, not broaden them.

Because claims 9 and 10 depend from claim 8, they are also seen to expand rather than further limit the claims from which they ultimately depend from and are objected to for the same reasons as set forth above.

Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. It is noted that claim 1 requires that the C5'-atom comprises an -OH group and claim 11 attempts to expand, and not limit claim 1, by indicating that the -OH group is no longer present and is coupled to a phosphate group to form a phosphate ester.

Dependent claims should limit the claims from which they depend, not broaden them.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 12-17 of copending Application No. 10/542,235. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming compounds overlapping in scope. It is noted that both applications also envision the same compounds, as both applications show in their examples the same compounds which are contemplated. It would be obvious to one of ordinary skill in the art at these two genus' are indeed overlapping and encompassing the same species of compounds.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

Claim 8 is drawn to a compound of claim 1 further comprising a moiety coupled to one

of the C2', C3', or C5' atoms thereby replacing the OH group wherein the moiety is

preferentially cleaved from the compound in a target cell or target organ. It is noted that the

claim fails to identify the moiety which is intended to be substituted. 35 USC 112 2nd paragraph

requires applicants to define their invention by particularly pointing out and distinctly claiming

their invention, and defining a moiety which is to be added to a structural core as one which is

cleaved in a target cell or target organ is not seen to clearly allow a skilled artisan to know what

the identity of the actual compound being claimed is. Moreover, the phrase "is preferentially

cleaved" is indefinite as it is unclear if the moiety actually has to be cleaved or not. Stating that

something is preferably done does not replace stating what a compound actually is. Additionally,

the phrase "in a target cell or target organ" is indefinite as it is unclear as to what organs or cells

are intended to be targets.

All claims which depend from an indefinite claim are also indefinite. Ex parte Cordova,

10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

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Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Walton et al. (US 3,480,613).

Claim 1 of the instant application is drawn to various 2'-substituted and 6-substituted adenosine nucleosides. Claim 2 provides that the compound comprises NR₁R₂ in the X position. Claim 3 provides that R₁ is optionally methyl, amino, or H and R₂ is optionally CH₂CH₂OH, CH₂CH₂NH₂, OCH₃, CH₃, or OH.

Walton et al. disclose compounds which meet the limitations of the above claimed compounds, specifically Walton et al. disclose in column 9 the following compounds:

- 9-(2-C-methyl-D-ribofuranosyl)-6-aminopurine,
- 9-(2-C-methyl-D-ribofuranosyl)-6-methylaminopurine,
- 9-(2-C-methyl-D-ribofuranosyl)-6-ethylaminopurine; and,
- 9-(2-C-methyl-D-ribofuranosyl)-6-dimethylaminopurine.

These compounds anticipate the compounds of claims 1-3 of the instant application wherein Z of the instant claims is methyl and X is amino, methylamino, ethylamino, and dimethylamino respectively. See column 9, lines 42, 45, 48, and 65.

Claims 8 and 11 are rejected under 35 U.S.C. 102(a) as being anticipated by La Colla et al. (US 6,812,219).

Claim 8 is drawn to a compound of claim 1 which optionally has various functionally defined moieties attached thereto. Claim 11 provides the compound of claim 1 comprises a phosphate group on the 5'-OH group to form a phosphate ester.

La Colla et al. disclose compounds meeting the limitations of the compounds claimed. Disclosed are phosphate esters in column 109-110, which comprise: R₁ is diphosphate; R₂=R₃=H; R₆ = CH₃; X=O; and the base is adenine. It is noted that the reference does not disclose the functionally defined compounds as set forth in claim 8, however, absent evidence to the contrary, and since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Traviss C. McIntosh III Art Unit 1623 July 6, 2006

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